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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,634	05/01/2001	Ick-Dong Yoo	1728/1F088-US1	5673

7590 10/30/2002

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AFREMOVA, VERA

ART UNIT	PAPER NUMBER
1651	(1)

DATE MAILED: 10/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/846,634</b>	Applicant(s) <b>Ick-Dong Yoo et al.</b>
	Examiner <b>Vera Afremova</b>	Art Unit <b>1651</b>
<b>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</b>		
<b>Period for Reply</b> A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.		
- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
<b>Status</b> <p>1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Aug 2, 2002</u></p> <p>2a) <input checked="" type="checkbox"/> This action is FINAL.      2b) <input type="checkbox"/> This action is non-final.</p> <p>3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11; 453 O.G. 213.</p>		
<b>Disposition of Claims</b> <p>4) <input checked="" type="checkbox"/> Claim(s) <u>4, 8, and 9</u> is/are pending in the application.</p> <p>4a) Of the above, claim(s) _____ is/are withdrawn from consideration.</p> <p>5) <input type="checkbox"/> Claim(s) _____ is/are allowed.</p> <p>6) <input checked="" type="checkbox"/> Claim(s) <u>4, 8, and 9</u> is/are rejected.</p> <p>7) <input type="checkbox"/> Claim(s) _____ is/are objected to.</p> <p>8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.</p>		
<b>Application Papers</b> <p>9) <input type="checkbox"/> The specification is objected to by the Examiner.</p> <p>10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).</p> <p>11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.</p> <p>12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.</p>		
<b>Priority under 35 U.S.C. §§ 119 and 120</b> <p>13) <input checked="" type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) <input checked="" type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input checked="" type="checkbox"/> Certified copies of the priority documents have been received in Application No. <u>03/771,261</u>. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</p> <p>*See the attached detailed Office action for a list of the certified copies not received.</p>		
<p>14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.</p> <p>15) <input checked="" type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</p>		
<b>Attachment(s)</b> <p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s)</p> <p>4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input checked="" type="checkbox"/> Other <b><i>translation of KR 97-15743</i></b></p>		

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## **DETAILED ACTION**

Claims 4 and 8 as amended and new claim 9 are pending and under examination. [Paper No. 8 filed 8/08/2002].

### ***Specification***

The disclosure is objected to because of the following informalities:

The address of the Korean Collection for Type Cultures (KCTC) is missing (see page 6, for example). Please, insert the current KCTC address.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

#### ***Deposit***

Claims 4 and 8 as amended and new claim 9 remain/is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention as explained in the prior office action and for the reasons below.

Applicants' statement with regard to the deposit requirement does not clearly identify what is material is deposited (see response page 3, last par.). The specification contains disclosure of several microorganisms belonging to *Phellinus linteus*, for example: see Figure 1. Therefore, it is not certain that statement relates to the strain KCTC 0399BP.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4 and 8 as amended and new claim 9 remain/is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. [U] taken with US 4,051,314 [IDS-1], US 4,877,777 [A] and KR 97-15743 [N] as explained in the prior office action and for the reasons below.

Claims are directed to a method for preparing a polysaccharide substance with immunostimulating activity wherein the method comprises step of culturing a fungal culture belonging to *Phellinus linteus* at temperature of about 28 °C for 5 days on media containing glucose, yeast extract and peptone in order to obtain mycelia; step of extracting the substance from the mycelia by hot water; step of isolating the substance by precipitation in ethanol for about 24 hours at temperature 4 °C, suspending in water, dialyzing at 10 °C for 72 hours and purifying the substance by using DEAE-cellulose chromatography and gel-chromatography. Some claims are further drawn to the use of a gradient elution in 0-1 M NaCl solution in the method for preparing the polysaccharide. Some claims are further drawn to a polysaccharide obtained by the claimed method wherein polysaccharide comprises glucose units joined by  $\alpha$  (1→4) and  $\beta$ (1→6) linkages.

The cited references are relied upon as explained in the prior office action and repeated herein.

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Lee et al. [U] disclose a fungal polysaccharide substance with immunostimulating activity and a method for preparing the polysaccharide substance wherein the method comprises step of culturing a fungal strain L13202 belonging to the fungal species of *Phellinus linteus* (page 326, col.1, last three lines) on media containing glucose, yeast extract and peptone (table 1, page 326) at temperature of about 30 °C for 12 days to obtain fungal mycelia; step of extracting the substance from the fungal mycelia with hot water (page 326, col. 2, last paragraph); step of isolating and purifying the substance by precipitation in ethanol at 4 °C overnight, suspending in water and dialyzing for 2 days (page 327, col. 1, lines 11-15). The cited reference teaches that polysaccharide substances derived from fungal cultures or mushrooms are characterized by immuno-stimulating activity or anti-tumor activity and that the fungal polysaccharide comprise glucose units and  $\beta(1\rightarrow6)$  linked branches (page 325, col. 1).

The cited reference by Lee et al. [U] is lacking particular disclosure related to purification steps such as the use of DEAE-cellulose chromatography and gel chromatography in a method for preparing a fungal polysaccharide substance from a fungal strain belonging to *Phellinus linteus*.

However, KR 97-15743 [N] teaches that an anticancer immunoactive polysaccharide substance derived from a fungal culture belonging to *Phellinus linteus*(see English title) strain KCTC 0173BP (see fig. 1) is prepared and purified by using DEAE-cellulose chromatography (see fig. 1) and gradient elution with 0.1-1 M NaCl (see official translation at page 6).

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In addition, US 4,051,314 [IDS-1] is relied upon to demonstrate conventional methods for polysaccharide production. It teaches that the fungal polysaccharide substances with immunostimulating activity or anticarcinogenic activity (abstract) are prepared from fungal cultures including cultures belonging to *Phellinus* sp. (see col. 6, example 1 or col. 22, example 18) wherein the method of preparation of fungal polysaccharide encompass step of incubating fungal culture for 20 days at 23°C -25 °C , steps of hot water extraction, precipitation in ethanol, suspending in water, dialysis as well as the use of purification procedures such as application of cellulose chromatography (col. 7, lines 12-40) and gel-chromatography or filtration (col.3, line 36-40).

US 4,877,777 [A] is relied upon for the teaching that the fungal polysaccharide substances which are characterized by immunobiological responses (col. 2, line 59) comprise glucose units joined by  $\alpha$  (1-4) and  $\beta$ (1-6) linkages (col. 2, lines 33-35 and col. 28, example 8).

In view of the teachings of the cited references, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the method for preparing polysaccharide substance derived from *Phellinus linteus* disclosed by Lee et al. [U] by applying purification steps including cellulose chromatography and gel-chromatography as taught by US 4,051,314 [IDS-1] and by KR 97-15743 [N] with a reasonable expectation of success in obtaining polysaccharide substances with immunostimulating effects because similar, if not identical, polysaccharide have been prepared and purified from fungal cultures belonging to *Phellinus* sp. {US 4,051,314 [IDS-1]} including *Phellinus linteus* {KR 97-15743 [N]} and

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because it is known that fungal polysaccharide substances with immunostimulating effects comprise glucose units joined by  $\alpha$  (1-4) and  $\beta$ (1-6) linkages {US 4,877,777 [A]}. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Applicants' arguments are directed to the idea that the presently claimed method is an optimized method for efficient production of polysaccharide from *Phellinus linteus* wherein an essential maximum production is reached after 5 days of incubation as demonstrated on Figure 2 and table VII in the instant specification (see response page 6, par. 2). Applicants appear to argue that the prior art references demonstrate longer periods of incubation in order to obtain a fungal mycelium which is a material for further polysaccharide extraction. These arguments are not found convincing with respect to the presently claimed invention. First, the applicants's figure 2 demonstrates incubation period which is more than 5 days. Moreover, the fungal culture accumulates larger amounts of fungal mycelium at the end of incubation period than after 5 days of incubation as demonstrated in the figure 2. Thus, it is reasonably believed that larger amounts of polysaccharide would be obtained from larger amounts of fungal mycelium. The table VII demonstrates amounts of polysaccharide only on day 5 of incubation. Therefore, the prior art methods which disclose incubation periods for more than 5 days do not teach away from the

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presently claimed invention, particularly in view that the prior art methods encompass the use the same species of fungal culture belonging to *Phellinus linteus* which is incubated in the similar media at the similar culture conditions. Therefore, the amounts of fungal mycelium or fungal polysaccharide are reasonably expected to be the substantially the same in methods of the cited references and in the applicants' method when both obtained after 5 days of incubation at 28 °C.

It has been noted in the prior office action that applicants conducted an extensive research for taxonomical identification and/or classification of the fungal strains belonging to *Phellinus linteus* including several ATCC strains and that they disclose the strain KCTC 0399BP as being a "novel" strain. However, it is uncertain what characteristics of the claimed strain KCTC 0399BP are intended by applicants as "novel" features (page 6, last line). It is also uncertain what are the differences between the claimed strain KCTC 0399BP and the other fungal strains including PL5, for example, which appears to be identical to KCTC 0399BP as disclosed (FIG. 1). It is uncertain what are the difference between the prior art fungal strains/polysaccharide and the applicants' fungal strains capable to produce polysaccharide substances of interest. Therefore, it is uncertain whether the use of the applicants' particular strain KCTC 0399BP might patentably distinguish over the state art as represented by the cited references which demonstrate the use the same species of fungal culture belonging to *Phellinus linteus* for the production of the polysaccharide at the similar conditions as in the presently claimed invention.

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With respect to the claim 8, drawn a composition as a product-by-process, it is noted that since the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

No claims are allowed.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova

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October 24, 2002.

*Irene Mirek*  
IRENE MIREK  
PRIMARY EXAMINER

*V.A.*